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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

001457

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE:

SUBJECT: Mutagenicity Tests of Garlon, EPA Reg. No. 464-546.
TPX Chem. No. 882I

FROM: William R. Schneider, Ph.D.
Toxicology Branch/HED (TS-769)

William R. Schneider

TO: Robert Taylor, PM #25
Registration Division (TS-767)

THRU: Edwin R. Budd, Section Head
Section II, Toxicology Branch/HED (TS-769)

Ed R. Budd
2/2/82

Chemical: Dowco 233 (Garlon)

Accession No.: 242367

Registrant: Dow Chemical (Nederland) B. V.
P. O. Box 1310
Aert van Nesstraat 45,
300 BH Rotterdam
Netherlands

Laboratory: Huntingdon Research Centre
Huntingdon, England

Study: Salmonella typhimurium reverse mutation assay

SUMMARY OF EVALUATION

1. No reverse mutations were induced by Dowco 233 at dosages from 10 to 10,000 ug/plate in the S. typhimurium reverse mutation assay using strains TA 1535, TA 1537, TA 1538, TA 98, and TA 100.

Study classification: 'Supplementary.'

2. Materials and Methods:

S. typhimurium strains TA 1535, TA 1537, TA 1538, TA 98, and TA 100 were treated with Dowco 233 in DMSO at dosage levels of 0, 10, 100, 1000 and 10,000 ug/plate. Each dosage level and the positive controls were performed in triplicate. Further details of methods are described in "HRC Protocol MCB/101" (not included with the submission).

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Results:

No increase in revertants or dose response effects were observed with or without metabolic activation in most of the assays, however, three showed some irregularities. Strains TA 1537 and TA 1538 showed slight increase with metabolic activation and strain TA 1535 without metabolic activation increased from 20 (at 0 ug/plate Dowco 233) to 65 revertant colonies per plate at 10,000 ug/plate Dowco 233. These three assays were repeated. No bacterial lawn was seen at 10,000 ug/plate Dowco 233 in both these repeat assays and in the TA 98 and TA 100 assays. No dose response effects or increase in revertants were produced in these repeated assays.

Positive controls (Sodium azide, 4-nitro-o-phenylene-diamine, 2-amino-anthracene, Neutral Red, and 2-acetyl-aminofluorene) produced elevated levels of revertants as expected (i.e. TA 1535 without activation had as much as 809 revertants/plate produced by 5 ug sodium azide/plate).

Summary of Evaluation:

No mutagenic effects were demonstrated in these bacterial strains treated with Dowco 233. The irregular effects observed initially with strains TA 1535, 1537, and 1538 were probably due to compound toxicity at the high dose levels. In some cases, the variation among the three replica plates at one dose level was as great as the total increase seen, therefore I believe that the repeat negative assays reflect the true situation in this case.

These assays are classified as supplementary since the method and materials details were not included, however, it appears to be thorough and well performed.

If Dow wishes to upgrade the study to "acceptable" they should send in the complete protocol. This is not necessary, however, since the Japanese Salmonella reverse mutation assay has been classified as acceptable and satisfies the requirement for this type of study.